

## Thanks for a Great Year!

The Immunization Program would like to thank you for all your efforts this past year in working to immunize Montana's children, adolescents, and adults. 2008 kept us all very busy with the Hib vaccine shortage, expanded influenza vaccine requirements, implementing the MT legislature's request to provide state-purchased HPV vaccine through public clinics (for non-VFC eligible patients), new vaccines, Vaccine Management Plans, updated VFC screening requirements, and our first full year on centralized distribution. Thanks for your work. 204,664 doses of vaccine were distributed through the MT Immunization Program. 2009 will prove to be no less busy with the continuation of the Hib vaccine shortage, more updated VFC policies, a changing economy, and many more things. We know the work is not easy and the immunization schedule is complex. We are here to assist you, please feel free to call us at 444-5580 or visit our website at [www.immunization.mt.gov](http://www.immunization.mt.gov).

## What's Happening in VFC

### Hib Shortage

We are sure everyone knows by now that there has been a shortage of Hib vaccine since Merck stopped selling PedvaxHIB® and Comvax® in December 2007. Merck had intended on returning to the market with these products during the final quarter of 2008. In October 2008, Merck released a statement indicating that they will not return to the Hib vaccine market until mid-2009.

So what does this really mean?

First, the Hib shortage schedule is still in effect. No booster doses of Hib are to be administered unless the child is at increased

risk for Hib disease, which includes American Indian and Alaska Native children. Specific details can be found on the VFC page on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov).

Second, with the introduction of Pentacel® this past summer, which contains ActHIB®, there has been a reduction in the number of single antigen doses of ActHIB® vaccine. Currently, MT does not receive enough single antigen Hib vaccine to fulfill all the doses we would typically use in a month for a three-dose schedule. However, when we add in Pentacel®, there is enough vaccine so that practices don't run out by the end of the month. Therefore, practices really need to look at implementing Pentacel® during the shortage. We know this complicates things, but vaccinating against Hib disease is too important not to try.

### Seasonal Influenza Vaccine

Some Flumist® doses just recently expired or will be expiring soon. For doses distributed through the MT Immunization Program, MedImmune has set up an exchange program. Notice was sent out to practices on 12/5/2008 and the information is posted on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov).

This exchange program is only available in multiples of 10. Do not discard or let these doses go to waste. The exchange program must be contacted no later than January 30, 2009 for replacement doses. Expired Flumist® not in multiples of 10, it should be returned through the normal VFC expired vaccine process. So, if you have 12 doses, exchange 10 and return 2 through VFC.

### Running Out of Vaccine?

With the implementation of centralized distribution, MT assigned practices to ordering frequencies (i.e., ordering monthly, bi-monthly, quarterly) and which months practices could order (i.e., some bi-monthly would be February, April, etc).

It is important that practices order within their assigned ordering frequencies. However, if you are running out of vaccine before the next time for the practice to order, please contact Home IV Pharmacy. We will work with the practice to get you more vaccine. We do not want practices borrowing vaccine unnecessarily. Depending on how often you order, we will likely just place your next order early and increase the amounts.

Please remember orders are evaluated and filled based on the practice's previous year's doses administered reports. If you have an increase in the number of patients you are seeing and need more vaccine, please let Home IV Pharmacy know when placing your order. Otherwise, we look at an average usage of the past year and may not detect recent increases.

### New Vaccines and New Licensure

It's been a busy year for new vaccines.

Pentacel® (DTaP-Hib-IPV) is licensed to be administered at 2, 4, 6, and 12-15 months (except because of the Hib shortage, this vaccine currently cannot be used for the 12-15 month dose).

Kinrix™ (DTaP-IPV) is licensed only for the booster doses of DTaP and IPV given between 4-6 years of age.

Rotarix® is to be administered orally in a 2-dose series with doses given at ages 2 and 4 months.

Boostrix® (Tdap) is now licensed to be administered to those aged 10-64.



### Are you or someone you love on the new CDC recommended influenza list?

For the first time this year, the CDC is recommending that virtually every child age 6 months to 18 years be vaccinated, unless they have a serious egg allergy. Why the change? Although children under 5 are more likely to be hospitalized, healthy school-age children have higher rates of influenza disease than other age groups. Plus, research increasingly shows that children are key spreaders of influenza (CDC Press Release, February 27, 2008).

Just 72 percent of people 65 and older were vaccinated in the 2006-07 flu season, even though Medicare pays for their doses. That's well short of the 2010 National Health Objective to vaccinate 90 percent of this age group (MMWR, September 26, 2008 Vol. 57, No. 38).

Also on CDC's get-vaccinated list: anyone 50 or older, women who are pregnant during flu season, health care workers, adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological, or metabolic disorders (including diabetes mellitus); adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV); adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration; residents of nursing homes and other chronic-care facilities; and healthy household contacts of any of the above groups (MMWR, August 8, 2008 Vol. 57, No. RR-7).

**Be sure to give influenza vaccine throughout the influenza season – through Spring 2009!**

## Needle Length Recommendations

A nurse in a Montana health department asked for comments on an article entitled, "Needle-Length Guidelines for Thigh and Shoulder Vaccinations May Need Revisions", written by Laurie Barclay, MD, and published on *Medscape Today*, August 14, 2008. The article recommends changes in needle length for injections. Here is the response to our query to the CDC's National Center for Immunization and Respiratory Diseases (NCIRD).

"This article is currently being discussed by the Advisory Committee on Immunization Practices. CDC has not changed its recommendations regarding needle length as published in the 2006 General Recommendations on Immunization [www.cdc.gov/mmwr/PDF/rr/rr5515.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf).

When determining IM needle length, please take into account site, age, technique. For adults, gender and body mass are important criteria as well. "

## New Guidelines for Influenza Antiviral Use

When influenza A (H1N1) virus infection or exposure is suspected, providers should consider the use of zanamivir or a combination of oseltamivir and rimantadine, in lieu of oseltamivir alone due to the identification of oseltamivir resistant strains early in the influenza season. For more details see

<http://www2a.cdc.gov/HAN/ArchiveSys/VieWMsgV.asp?AlertNum=00279>.

## What is VAERS?

The Vaccine Adverse Event Reporting System (VAERS) is a national program that monitors the safety of vaccines after they are licensed. VAERS is managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

- Before a vaccine is licensed, FDA takes steps to make sure the vaccine is safe.

- To do this, FDA requires that a vaccine goes through extensive safety testing, although rare side effects may not be identified in the relatively small number of persons who receive vaccine in these FDA monitored trials.
- After a vaccine is licensed, VAERS is one of the mechanisms used to monitor for "adverse events," that may not have been identified in the safety trials as well as the side effects that were documented in those trials.

Not all events reported to VAERS are caused by the vaccine. Even though careful studies are done before a vaccine is licensed, rare adverse effects may not be found until a vaccine is given to millions of people with different backgrounds and medical histories. VAERS helps to make sure that the benefits of vaccines are far greater than the risks.

- Anyone who receives a vaccine should be informed about both the benefits and risks of vaccination.
- Any questions or concerns should be discussed with a healthcare provider.

## Limitation and Usefulness of VAERS

VAERS is unable to determine that a vaccine caused or did not cause an adverse event. Sometimes people who are vaccinated get sick from another cause unrelated to the vaccine.

- Information from VAERS can give FDA and CDC important information that might signal a problem.
- If it looks as though a vaccine might be causing an adverse event, FDA and CDC will investigate further.

## Does VAERS Provide Medical Advice?

No, VAERS does not provide medical advice.

## Who Can Report to VAERS?

FDA and CDC encourage anybody who experiences any problems after vaccination to report to VAERS.

## Why Should I Report to VAERS?

- Reporting gives valuable information that helps CDC and FDA make sure that vaccines are as safe as possible.

- Reporting strengthens VAERS so it can be used to assess public health response to vaccines.
- Reporting allows for evaluating public health prevention and control measures.

Remember, no vaccine (or any medicine) is completely free of risk and adverse events are possible. If you have an adverse event after a vaccine, please report to VAERS.

### What Types of Events Should I Report?

You should report any adverse health event that happens after receiving a vaccine, even if you are not sure that the adverse event was related to the vaccine.

- It is especially important to report any adverse event that resulted in hospitalization, disability, or death.
- If you are not sure that a certain type of adverse event should be reported to VAERS, talk with your healthcare provider.

Healthcare providers are required by law to report certain adverse events. To get a list of these, or if you have any other questions, please call Tim Horan at the Immunization Program at 444-1613, the VAERS Program at 1-800-822-7967 or go to [www.vaers.hhs.gov/reportable.htm](http://www.vaers.hhs.gov/reportable.htm).

### How Do I Report?

It's very easy to report to VAERS. You can report on-line at <https://secure.vaers.org>, fax a completed report form to 1-877-721-0366 (toll-free) or, mail a completed report form to VAERS, P.O. Box 1100 Rockville, MD, 20849-1100. After you submit a report, VAERS staff may contact you for additional information.



### “Lost to Follow-up” Hepatitis B Cases

If your client has moved or “disappeared,” every attempt must be made to trace them so that a referral can be made to the new location.

- When talking with the client (during the first encounter) ask about any plans to

move and who you could talk to about their whereabouts.

- Try old telephone numbers, old neighbors.
- Send SASE requesting new location to old address & it may be forwarded.
- Check with the client's provider or agencies that have provided services to the client, (the name of a town or county is really helpful).
- Give whatever you have learned to the appropriate State program for final referral.
- It is essential to follow-up for all clients with reportable diseases to provide needed referrals and prevent further transmission of disease.

### Hepatitis B Testing & Follow-up

Pregnant mothers that are not being tested for Hepatitis B Surface Antigen in each pregnancy are not getting reported to either state or local public health departments for infant case management and contact follow-up. This can result in a “missed baby” with hepatitis B infection, possibly with tragic results.

The law requiring prenatal blood testing is designed to prevent transmission of hepatitis B virus (HBV) to the newborn by identifying the mother's status. Testing only “high risk” mothers allows HBV-infected pregnant women to be missed. Relying on a risk assessment or the HBsAg status from a prior pregnancy can be deceptive. Case management programs are crucial to ensure prevention of perinatal HBV infections and its consequences. In addition, the law requires blood testing for each pregnancy. This does not mean risk assessment is not necessary as well. A mom who tests negative early in pregnancy and is high risk should be tested again close to the due date to discover if she became infected during the pregnancy. Pregnant women who tested HBsAg positive on previous pregnancies must be tested with each pregnancy. Once identified, contact investigation is updated; the infant receives post-exposure prophylaxis beginning at birth and continues to be followed.



***A copy of the original laboratory report, (not a checklist or note) on both the mother's and baby's hospital chart must be included.*** Transcription errors have been documented when using other than a copy of the original. Because of errors like this babies have been infected.

The Centers for Disease Control and Prevention (CDC) in Managing a Perinatal Hepatitis B Program, April 2007 explains:

- ❖ **All pregnant women are tested for HBsAg during each pregnancy.**
- ❖ All positive HBsAg results are reported to state or local health departments.
- ❖ HBsAg test results (positive or negative) are to be included on all forms (hard and electronic) used by practitioners to record and transmit information about care during pregnancy
- ❖ For all pregnant women, a copy of the **original** lab report of HBsAg results is transferred from provider to delivery hospital; the transfer is documented. The lab copy is placed in **both** the mother's and the baby's chart.

The statutes may be found at Montana Code Annotated (MCA) – 2007. MCA 50-19-101 through 50-19-103

#### **The Administrative Rules of Montana 37.114.540 (2)**

A summary of the above statute states: In the event a hepatitis B surface antigen (HBsAg) is positive in a pregnant woman, the local health office must: ensure that appropriate ...providers and birthing facility are aware of mother's status and need for infant prophylaxis, b) ensure HBIG and HBV vaccine availability at the delivery hospital, c) confirm administration of vaccine and HBIG after birth; inform mother of follow-up, d) at 1–2 months and at 6 -7 months of infant's age confirm the vaccine was given and obtain report, e) at 9 -15 months ,confirm testing of the infant for **surface antigen and antibody** to the hepatitis B virus (HBV). Counsel as needed and submit reports. Contact Nancy Demoro 444-1805.

## **Recording Lot Numbers for Vaccines with Multiple Lot Numbers**

On October 3, 2008 the MMWR (<http://www.cdc.gov/mmwr/PDF/wk/mm5739.pdf>) said: "Different lot numbers for different components of DTaP-IPV/Hib are included on the DTaP-IPV vial and on the Hib powder vial. Providers should record lot numbers separately for the DTaP-IPV and Hib components."

Pentacel® should be kept together in its original box and the DTaP-IPV vaccine should only be used to reconstitute the lyophilized Hib component. If Pentacel® is used as it is supplied, there is no need to record both numbers. However, if the DTaP-IPV component is used to reconstitute a vial of ActHIB® that was not supplied in the same box, then both lot numbers need to be recorded.

## **ACIP Posts Provisional Pneumococcal Recommendations**

On October 22, 2008, the ACIP voted on new and revised recommendations for the use of 23-valent pneumococcal polysaccharide vaccine (PPSV23).

Recommendations include vaccinations for cigarette smokers and adults with asthma. Also included are revised recommendations for American Indians and Alaska Natives and revaccination of high-risk children aged  $\leq 10$  years. "A second dose of PPSV23 is recommended 5 years after the first for persons aged  $\geq 2$  years who are immunocompromised, have sickle cell disease, or functional or anatomic asplenia."

Details can be found at:

<http://www.cdc.gov/vaccines/recs/provisional/default.htm>

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## **Regional Immunization**

### **Workshop dates:**

**Great Falls** February 12, 2009

**Missoula** February 24, 2009

**Butte** February 26, 2009

**Miles City** March 10, 2009

**Billings** March 12, 2009



## **THE READING WELL**

To Order More Books - Contact: John Hoffland, Medicaid Program at 444-9538 or the Immunization Program at 444-5580.



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